

REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 1-38 and 49-64 pending and under consideration. It is believed that this Amendment and Reply addresses and overcomes all rejections made in the Office Action. Reconsideration and allowance of the application are therefore requested.

Claims 1, 58 and 64 stand rejected under 35 U.S.C. 112, first paragraph, based on the statement in the Office Action that they fail to comply with the written description requirement. In support, the Office Action notes that claims 1 and 64 use the term "plasticizer" and asserts that the specification does not adequately describe the term. In response, Applicant notes that it is well established that "a patent need not teach, and preferably omits, what is well known in the art". *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987). In the present case, plasticizers are well known to those of ordinary skill in the art. The Office Action itself confirms this point in the discussions spanning pages 2-3. Accordingly, the term plasticizer is adequately described, and withdrawal of this rejection as to claims 1 and 64 is solicited.

As to claim 58, the Office Action did not give any reason why this rejection was applied. Further, claim 58 contains no term that is not adequately described in the specification. Withdrawal of the rejection is thus solicited.

Claim 58 stands rejected under 35 U.S.C. 112, second paragraph, based on the statement in the Office Action that it fails to particularly point out and distinctly claim the invention. In support, the Office Action notes the use of the term "diluent". However, the Office Action does not set forth any reason why the metes and bounds of the term would be unclear to one skilled in the art. To the contrary, as noted in the Office Action, the term is one that is known to and

commonly used by those of ordinary skill in the art. Further, claim 58 has been amended to specify an “aqueous diluent”. Accordingly, withdrawal of this rejection is solicited.

Claims 1-17, 19-23, 26-28, 31, and 49-57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sybert et al. in view of Boyce et al. This rejection is respectfully traversed to the extent maintained against any remaining claim.

Sybert et al. is relied upon in the Office Action for its teaching that “the mechanical strength of demineralized bone ... can be increased by forming chemical linkages between adjacent bone particles by exposing collagen on adjacent bone particles and forming collagen-collagen bonds.” Boyce et al. is relied upon because it states “that bone particles can be combined with one or more biocompatible components, such as plasticizers...”. From these teachings, the Office Action states that “It would have been obvious to a person having ordinary skill in the art to make a composition comprising crosslinked DBM and collagen because Sybert et al. states that the mechanical strength of DBM can be increased by forming chemical linkages between adjacent bone particles by exposing collagen on adjacent bone particles and forming collagen-collagen bonds, and further to improve the composition as suggested by Boyce et al...”. However, even if this proposed combination were made, one would not have the compositions as presently claimed in the rejected claims. Claims 1 and 49 as amended, the independent claims in the group, both expressly require that the collagen be “from a source other than said demineralized bone matrix”. The combination proposed in the Office Action would not achieve that result. Accordingly, withdrawal of this rejection is solicited.

At pages 7-10 of the Office Action, various claims dependent on claim 1 are rejected under 35 U.S.C. § 103 as being obvious over Sybert et al. and Boyce et al. further in combination with selected ones of several secondary

references, including Simpson et al., Fang et al., Bucala et al., Chilkoti et al., and Boyce et al '041. In each case, the tertiary reference is relied upon as teaching a specific crosslinking agent or material for incorporation in the composition. None of these references, alone or combined with the Sybert et al. and Boyce et al. references, positively motivates one of ordinary skill in the art to make the combination of features provided in independent claim 1 as amended or independent claim 49 as amended and the respective dependent claims against which the references are applied. Accordingly, it is submitted that these various rejections of dependent claims under 35 U.S.C. § 103 are also overcome and should be withdrawn.

Claims 58-64 stand rejected under 35 USC 103(a) based upon a statement in the Office Action that they are unpatentable over Sybert et al. in view of Boyce et al. taken further in view of McKay. To any extent maintained, this rejection is respectfully traversed for the following reasons.

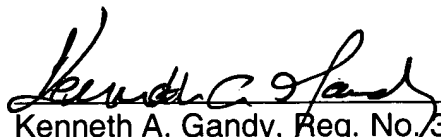
Proper rejections under 35 USC 103 must not involve the use of hindsight and must include a clear recitation of motivation, drawn from the references themselves and not from Applicant's disclosure, to make the combination proposed by the Patent Office. Here, it is submitted that that stated rejection made, and to the extent maintained, clearly uses hindsight analysis taking Applicant's own disclosure into account, and does not identify any motivation drawn from the references themselves to make the combination. Particularly, in one aspect the rejection relies upon the isolated Boyce et al. teachings relative to preparing a paste composition and asserts that one skilled in the art would use this paste teaching "to improve upon the design" of Sybert et al.'s solid products. It is respectfully submitted that there is absolutely no teaching from the references that such a modification would be considered to "improve upon the design" of Sybert et al. Sybert et al. relates to a band structure for repairing spinal disorders. In fact, both Sybert et al. and Boyce et al. teach end products that are solid forms, not pastes! (The Boyce et al. product is load bearing with

high compressive strength). Accordingly, no motivation exists in the references themselves for the proposition of "improvement" made in the Office Action, and that motivation could only have been drawn from the Applicant's specification. Further, it is noted that claim 58 as amended is directed to "a sterile osteoinductive composition in a paste form". The paste form in Boyce et al. is only a temporary intermediate product in the manufacture of solid, load-bearing device. There is no teaching or suggestion in Boyce et al., and no motivation, to sterilize that intermediate paste product of Boyce et al. For these reasons, it is submitted that the stated rejection in the Office Action is not properly supported, and should be withdrawn.

In view of the foregoing amendments and remarks, it is submitted that this application is in condition for allowance containing claims 1-38 and 49-64. Prompt such action is requested. The Examiner is invited to telephone the undersigned attorney if there are any questions about this Amendment and Reply or other matters that might be handled in that fashion to expedite the allowance of this application.

Respectfully Submitted,

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